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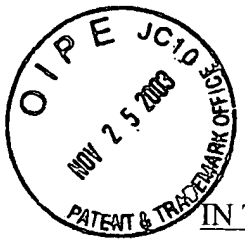

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Richard B. North; Jeffrey M. Sieracki; David D. Brigham	Confirmation No.	Unknown
Serial No.:	10/696,501		
Filed:	October 29, 2003	Customer No.:	28863
Examiner:	Unknown		
Group Art Unit:	Unknown		
Docket No.:	1023-223US01		
Title:	IMPLANTABLE NEUROSTIMULATOR PROGRAMMING WITH BATTERY LONGEVITY INDICATION		

CERTIFICATE UNDER 37 CFR 1.8: I hereby certify that this correspondence is being deposited with the United States Post Service, as First Class Mail, in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313-1450 on November 21, 2003.

By: Shirley A. Betlach
Name: Shirley A. Betlach

PETITION TO CORRECT FILING DATE PURSUANT TO 37 C.F.R. § 1.10(c)

Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

The above-captioned patent application, which is attached as Exhibit A, was deposited with the United States Postal Service (USPS) on October 29, 2003. However, a recently received postcard receipt, which is attached as Exhibit B, incorrectly indicates an October 30, 2003 filing date for the application. Consequently, Applicants believe that the Office will accord a filing date for the application other than its USPS deposit date, and are promptly petitioning the Commissioner to accord the application the October 29, 2003 USPS deposit date as its filing date.

A true copy of the Express Mail mailing label for the application, number ET987500483US, is attached as Exhibit C. The Express Mail mailing label indicates that the "date-in", i.e., the date of deposit with the USPS, was October 29, 2003. The number of the

Express Mail mailing label, ET987500483US, was placed on both the transmittal form for the Patent Application (Exhibit A) and the postcard receipt (Exhibit B) prior to their deposit with the USPS on October 29, 2003.

A copy of a sales receipt received from the USPS is attached as Exhibit D. Highlighted portions of the sales receipt include the number of the Express Mail mailing label for the application and the October 29, 2003 deposit date, further demonstrating that the application was deposited with the USPS on October 29, 2003.

In conclusion, having demonstrated that there is a discrepancy between the filing date that the Office will likely accord the above-captioned patent application and its date of deposit with the USPS, Applicants request that the Commissioner accord the application its date of deposit with the USPS, October 29, 2003, as its filing date.

Date: November 21, 2003

By: Jason D Kelly

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OIPE JC10 NOV 25 2003 PATENT & TRADEMARK OFFICE

Exhibit A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Richard B. North; Jeffrey M. Sieracki; David D. Brigham		
Filed:	Herewith	Customer No.:	28863
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CERTIFICATE UNDER 37 CFR 1.10: ET 987500483 US
"Express Mail" mailing label number: ET987500483US
Date of Deposit: October 29, 2003

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, Alexandria, VA 22313-1450.

By: Shirley A. Betlach
Name: Shirley A. Betlach

NEW PATENT APPLICATION UNDER 37 C.F.R. § 1.53

MAIL STOP PATENT APPLICATION
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

This application claims priority from U.S. Provisional Application Serial No. 60/448,457, filed February 21, 2003 and U.S. Provisional Application Serial No. 60/503,207, filed September 15, 2003.

Presented for filing is a new patent application. Enclosed are the following papers, including those required to receive a filing date under 37 CFR §1.53(b):

- ☒ Transmittal sheet containing Certificate of Mailing
- ☒ Utility Patent Application: Spec. 14 pgs; claims 10 pgs; Abstract 1 pg.
- ☒ 6 sheets of formal drawings.
- ☒ Combined Declaration and Power of Attorney (4 pgs.)
- ☒ Assignment including Recordation Form Cover Sheet
- ☒ Assignment (2 pgs.)
- ☒ Return postcard

CLAIMS

Number of Claims Filed		In Excess of:		Extra		Rate		Fee
Basic Filing Fee								$770.00
Total Claims								
58		20		38	x	$18.00	=	$684.00
Independent Claims								
3		3		0	x	$86.00	=	$
MULTIPLE DEPENDENT CLAIM FEE								
TOTAL FILING FEE								$1454.00

Under 37 CFR §1.53(f), no filing fee is being paid at this time.

If this application is found to be incomplete, or if a telephone conference would otherwise be helpful, please call the undersigned at (651) 735-1100.

Kindly acknowledge receipt of this application by returning the enclosed postcard.

Please send all correspondence to Practitioners at Customer Number 28863.

28863
PATENT TRADEMARK OFFICE

Respectfully submitted,

Date: October 29, 2003

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IMPLANTABLE NEUROSTIMULATOR PROGRAMMING WITH BATTERY LONGEVITY INDICATION

[0001] This application claims priority from U.S. Provisional Application Serial No.60/448,457, filed February 21, 2003, and U.S. Provisional Application Serial No.60/503,207, filed September 15, 2003. The entire content of both Provisional Applications is incorporated herein by reference.

TECHNICAL FIELD

[0002] The invention relates to implantable neurostimulators, and more particularly to programming of implantable neurostimulators.

BACKGROUND

[0003] Implantable neurostimulators are used to deliver neurostimulation therapy to patients to treat a variety of symptoms or conditions such as chronic pain, tremor, Parkinson's disease, epilepsy, incontinence, or gastroparesis. Typically, implantable neurostimulators deliver neurostimulation therapy in the form of electrical pulses via leads that include electrodes. To treat the above-identified symptoms or conditions, for example, the electrodes may be located proximate to the spinal cord, pelvic nerves, or stomach, or within the brain of a patient.

[0004] A clinician may select values for a number of programmable parameters in order to define the neurostimulation therapy to be delivered to a patient. For example, the clinician may select a voltage or current amplitude and pulse width for a stimulation waveform to be delivered to the patient, as well as a rate at which the pulses are to be delivered to the patient and a duty cycle. The clinician may also select as parameters particular electrodes within the electrode set carried by the leads to be used to deliver the pulses, and the polarities of the selected electrodes. A group of parameter values may be referred to as a program in the sense that they drive the neurostimulation therapy to be delivered to the patient.

[0005] Typically, a clinician selects parameter values for a number of programs to be tested on a patient during a programming session using a programming device. The programming device directs the implantable neurostimulator implanted in the patient to deliver

neurostimulation according to each program, and the clinician collects feedback from the patient, e.g., rating information, for each program tested on the patient. The clinician then selects one or more programs for long-term use by the implantable neurostimulator based on the rating information. Some programming devices automatically present programs defined by the clinician to the INS, and collect feedback from the patient. One such programming device is described in U.S. Patent No. 6,308,102, issued to Sieracki et al., which is incorporated herein by reference in its entirety.

[0006] Implantable neurostimulators typically include a nonrechargeable battery that provides power for delivery of neurostimulation. The longevity of the battery depends on the parameters of the program selected by the clinician for long-term delivery of neurostimulation. In particular, the battery longevity is inversely proportional to the pulse amplitude, pulse rate, pulse width, and duty cycle specified by the program, and to the load presented to the battery. Generally speaking, the load presented to the battery depends on the number of electrodes specified by the program for delivery of neurostimulation.

[0007] When the battery of an implantable neurostimulator is depleted, the implantable neurostimulator must be explanted from the patient and replaced. Replacement of an implantable neurostimulator is costly, and because it requires a surgical procedure the patient incurs risks associated with surgery. Nonetheless, clinicians typically do not consider battery longevity, e.g., the amount of time an implantable neurostimulator will be able to deliver neurostimulation according to a program before its battery expires, when selecting programs from among those tested during a programming session. This is despite the fact that battery longevities can vary greatly among the programs tested, e.g., from on the order of months up to two or more years.

SUMMARY

[0008] In general, the invention is directed toward techniques for presenting battery longevity information to a user during a programming session for programming an implantable neurostimulator (INS). A programming device directs the INS to deliver neurostimulation therapy according to a plurality of programs during the programming session. The programming device estimates a battery drain rate for each of the tested programs. In some embodiments, the programming device estimates a battery longevity for

each of the tested programs based on the estimated drain rate, e.g., estimates a length of time that the INS will be able to deliver neurostimulation according to the program before the INS must be explanted and replaced due to battery depletion.

[0009] Each of the programs includes parameters that define the neurostimulation delivered according to that program. For example, each program may include as parameters a voltage or current pulse amplitude, a pulse width, a pulse rate, and a duty cycle. The program may also identify as parameters the electrodes selected from a set coupled to the INS and their polarities, e.g., anode or cathode, for delivery of neurostimulation according to that program. The programming device estimates battery drain rates for each of the programs tested during the programming session based on the parameters for that program.

[0010] In particular, the programming device estimates the battery drain for a program based on the program parameters that define the neurostimulation waveform, and an estimate of the load presented to the battery during delivery of the neurostimulation waveform. In some embodiments, the programming device estimates the load based on the number of anodes and cathodes for the program, and an assumed per-electrode impedance. In some embodiments, the programming device alternatively or additionally estimates the load based on device configuration information, such as an INS type, lead type, and/or electrode locations. The programming device may receive the device configuration information from the user, and identify components of the total load presented to the battery from look-up tables based on the received device configuration information. In other embodiments, the programming device may direct the INS to measure the impedance presented by each electrode coupled thereto, receive the measured impedance values, and determine the load for a particular program based on the impedances for the anodes and cathodes selected for that program.

[0011] In some embodiments, the estimated battery drain rates are presented to the user within a listing of the programs. In other embodiments, a listing of battery longevities is presented instead of or in addition to the drain rates. The programming device may estimate battery longevities based on the estimated drain rates and the capacity of the battery, which may be determined from a look-up table based on device type information received from the user. Alternatively, the programming device may calculate battery longevities given the estimated drain rates, the capacity of the battery and one or more equations that determine battery longevity. The battery longevities may be presented to the user as, for example, an

estimated number of years or months until explant. The listing may be ordered according to the battery drain rates and/or battery longevities to allow a user to select a program that provides a low drain rate and high longevity.

[0012] In some embodiments, the programming device additionally receives rating information for each of the programs tested during the programming session. The rating information may include, for example, an effectiveness score and/or an estimation of the overlap of a pain area of the patient with a paresthesia area resulting from delivery of neurostimulation according to the program. In exemplary embodiments, the rating information is presented alongside the battery drain rates and/or longevities within the list, and the user may select to order the list according to either the rating information or the battery longevity information.

[0013] In one embodiment, the invention is directed to a method in which an implantable neurostimulator is directed to deliver neurostimulation according to a plurality of programs during a programming session, each of the programs including a plurality of parameters that define delivery of neurostimulation according to that program. A battery drain rate is estimated for each of the programs based on the parameters for that program, and battery longevity information is presented to a user based on the estimated battery drain rates.

[0014] In another embodiment, the invention is directed to a programming device that includes a telemetry circuit, a user interface, and a processor. The processor directs an implantable neurostimulator to deliver neurostimulation according to a plurality of programs during a programming session via the telemetry circuit, each of the programs including a plurality of parameters that define delivery of neurostimulation according to that program. The processor estimates a battery drain rate for each of the programs based on the parameters for that program, and presents battery longevity information to the user based on the estimated battery drain rates.

[0015] In another embodiment, the invention is directed to a computer-readable medium containing instructions. The instructions cause a programmable processor to direct an implantable neurostimulator to deliver neurostimulation according to a plurality of programs during a programming session, each of the programs including a plurality of parameters that define delivery of neurostimulation according to that program, estimate a battery drain rate

for each of the programs based on the parameters for that program, and present battery longevity information to a user based on the estimated battery drain rates.

[0016] The invention may provide advantages. For example, by presenting battery longevity information, a programming device according to the invention may allow a clinician to select a program for long-term use from among programs tested that provides greater battery longevity than a program selected based on efficacy alone. Battery longevity may vary widely among tested programs that provide similar efficacy. Consequently, a programming device according to the invention may allow a clinician to identify a program that strikes a desirable balance between battery longevity and efficacy. By presenting the battery drain rates and/or longevities and the rating information in a single sortable list, the programming device may allow the clinician to more easily identify such a program. Further, by allowing the clinician to select a program that provides a greater battery longevity than a program selected based on efficacy alone, the programming device may allow explanation and replacement of an implantable neurostimulator to be delayed relative to the time at which they would have occurred if a program had been selected without regard to battery longevity.

[0017] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0018] FIG. 1 is a conceptual diagram illustrating an exemplary environment in which battery longevity information is presented to a user during a programming session according to the invention.

[0019] FIG. 2 is a block diagram illustrating an example implantable neurostimulator.

[0020] FIG. 3 is a block diagram illustrating an example programming device that presents battery longevity information during a programming session according to the invention.

[0021] FIG. 4 is a conceptual diagram illustrating an example graphical user interface that the programming device of FIG. 3 may present to a user.

[0022] FIG. 5 is a flow diagram illustrating an example operation of the programming device of FIG. 3 to present battery longevity information to a user during a programming session.

[0023] FIG. 6 is a flow diagram illustrating another example operation of the programming device of FIG. 3 during a programming session.

DETAILED DESCRIPTION

[0024] FIG. 1 is a conceptual diagram illustrating an exemplary environment 10 in which battery longevity information is presented to a user during a programming session according to the invention. Environment 10 includes an implantable neurostimulator (INS) 12, which is shown in FIG. 1 implanted within a patient 14. INS 12 delivers neurostimulation therapy to patient 14 via leads 16A and 16B (hereinafter "leads 16").

[0025] In the illustrated configuration, leads 16 are implanted proximate to the spinal cord 18 of patient 14, and INS 12 delivers spinal cord stimulation (SCS) therapy to patient 14 in order to, for example, reduce pain experienced by patient 14. Leads 16 include electrodes (not shown in FIG. 1), and INS 12 delivers neurostimulation to spinal cord 18 via the electrodes. INS 12 may be an implantable pulse generator, and may deliver neurostimulation to spinal cord 18 in the form of electrical pulses.

[0026] INS 12 delivers neurostimulation according to a program. The program may include values for a number of parameters, and the parameter values define the neurostimulation therapy delivered according to that program. In embodiments where INS 12 delivers neurostimulation therapy in the form of electrical pulses, the parameters include voltage or current pulse amplitudes, pulse widths, pulse rates, duty cycles, and the like. Further, the parameters for a program include information identifying which electrodes have been selected for delivery of pulses according to the program, and the polarities of the selected electrodes, e.g., anode or cathode.

[0027] Environment 10 also includes a programming device 20. Programming device 20 may, as shown in FIG. 1, be a handheld computing device. Programming device 20 includes a display 22, such as a LCD or LED display, to display information to a user. Programming device 20 may also include a keypad 24, which may be used by a user to interact with programming device 20. In some embodiments, display 22 may be a touch screen display, and a user may interact with programming device 20 via display 22. A user may additionally or alternatively interact with clinician programmer 20 using peripheral pointing devices, such

as a stylus or mouse. Keypad 24 may take the form of an alphanumeric keypad or a reduced set of keys associated with particular functions.

[0028] A clinician (not shown) may use programming device 20 to program neurostimulation therapy for patient 12. In some embodiments, the clinician specifies programs by selecting program parameter values, tests the specified programs on patient 12, and receives feedback, e.g., rating information, for each of the tested programs from the patient. The clinician enters the feedback into programming device 20.

[0029] In other embodiments, programming device 20 provides an automated or semi-automated programming routine in which programming device 20 automatically tests clinician specified programs or programs automatically generated by programming device 20 on patient 14. In such embodiments, either or both of the clinician and patient 14 may interact with programming device 20 during testing of the generated programs to, for example, enter rating information for each of the programs. An exemplary programming device that provides a semi-automated programming routine is described in U.S. Patent No. 6,308,102, issued to Sieracki et al.

[0030] In either case, programming device 20 sends each of the programs to be tested to IMD 12 using radio-frequency (RF) telemetry techniques known in the art. For example, programming device 20 may send program parameters as commands, and may send other commands necessary to effect reprogramming of IMD 12 via device telemetry. IMD 12 receives and decodes the commands, and stores the program parameters in registers, or the like, for use in defining the neurostimulation delivered to patient 14 according to that program.

[0031] INS 12 includes a battery (not shown in FIG. 1) that provides power for delivery of neurostimulation energy and other functions performed by INS 12, e.g., processing, memory and telemetry functions. Delivery of neurostimulation energy, however, accounts for by far the most significant drain on the battery of INS 12. The drain on the battery of INS 12 caused by delivery of neurostimulation according to a program depends on the parameters of that program, e.g., the pulse amplitude, width and rate, duty cycle, and the combination of electrodes selected for delivery neurostimulation according to the program.

[0032] As will be described in greater detail below, programming device 20 estimates a battery drain rate for each of the programs tested based on the program parameters. In some

embodiments, programming device 20 presents the estimated battery drain rates for programs tested during the programming session. In other embodiments, programming device 20 further estimates a battery longevity for each of the tested programs, e.g., estimates a length of time that INS 12 will be able to deliver neurostimulation according to the program before INS 12 must be explanted and replaced due to battery depletion. The estimated battery longevity may be based on the estimated battery drain rates. Programming device 20 may present the battery longevities to the clinician in addition to or instead of presenting the battery drain rates. By presenting one or both of the battery drain rates and longevities, programming device 20 allows the clinician to consider battery longevity when selecting one or more programs, and to select programs from among those tested that provide favorable drain rates and longevities. In this manner, the clinician may take into account not only the efficacy and side effects associated with a particular neurostimulation program, but also power consumption.

[0033] FIG. 2 is a block diagram illustrating an example configuration of INS 12. INS 12 may deliver neurostimulation therapy via electrodes 30A-D of lead 16A and electrodes 30E-H of lead 16B (collectively "electrodes 30"). Electrodes 30 may be ring electrodes. The configuration, type, and number of electrodes 30 illustrated in FIG. 2 are merely exemplary.

[0034] IMD 16 includes a therapy delivery circuit 32. Electrodes 30 are electrically coupled to therapy delivery circuit 32 via leads 16. Therapy delivery circuit 32 may, for example, include an output pulse generator. Therapy delivery circuit 32 delivers electrical pulses to patient 14 via at least some of electrodes 30 under the control of a processor 34.

[0035] Processor 34 controls therapy delivery circuit 32 to deliver stimulation according to program stored with a memory 38. Specifically, processor 34 controls therapy delivery circuit 32 to deliver electrical stimulation pulses with an amplitude, width, and rate specified by the program, and may activate therapy delivery circuit 32 to deliver stimulation pulses according to a duty cycle specified by the program. Processor 34 also controls circuit 32 to deliver the pulses via a selected subset of electrodes 30 with selected polarities, as specified by the program.

[0036] As described above, INS 12 may be reprogrammed a number of times during a programming session to test a number of programs. For each program tested, INS 12 receives a number of commands, including the program parameters, from programming

device 20 via a telemetry circuit 36 that allow processor 34 to communicate with programming device 20 via wireless telemetry techniques known in the art. The program parameters are stored within a memory 38 as the program used by processor 34 to control delivery of neurostimulation. Processor 34 may include a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), discrete logic circuitry, or the like. Memory 38 may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, and the like.

[0037] As shown in FIG. 2, INS 12 includes a battery 40. Battery 40 may be a non-rechargeable, e.g., primary, battery. Battery 40 may take the form of any of a variety of lithium-ion batteries well known in the implantable medical device arts. Battery 40 is illustrated in FIG. 2 as providing power to therapy delivery circuit 32 for generation of stimulation pulses. Although not illustrated in FIG. 2, battery 40 may provide power to each of components 32-38 of INS 12. However, as indicated above, delivery of energy necessary to support neurostimulation therapy by therapy delivery circuit 32 represents by far the most significant drain on battery 40.

[0038] In some embodiments, INS 12 may also, as shown, include an impedance measurement circuit 42 to measure the impedance at each of electrode 30. Impedance measurement circuit 42 may include any circuits and apply any techniques known in the implantable medical device arts for measuring impedances, such as measuring the change in voltage across a capacitor during delivery of a pulse, to determine the impedance for each of electrodes 30. Processor 34 may control impedance measurement circuit 42 to measure impedances for electrodes 30 upon receiving a command from programming device 20, and may provide the measured impedances to programming device 20 via telemetry circuit 36 for calculation of battery drain rates, as will be described in greater detail below with reference to FIG. 3

[0039] FIG. 3 is a block diagram illustrating an example configuration of programming device 20. Programming device 20 includes a processor 50 and a user interface 52 that allows a user, such as the clinician or patient 14, to interact with processor 50. User interface 52 may include display 22 and keypad 24 (FIG. 1), and allow the clinician or patient 14 to,

for example, specify parameters for a number of programs 54 to test during a programming session, provide rating information 56 for tested programs, and view rating information 56 and battery longevity information 58 for each of the tested programs.

[0040] Processor 50 provides programs 54 to INS 12 for testing via a telemetry circuit 60, which allows processor 50 to communicate with INS 12 according to wireless telemetry techniques known in the art. Processor 50 stores programs 54 specified by the clinician within a memory 62 of programming device 20. Rating information 56 and longevity information 58 for each of the programs is stored within memory 62 in association with the respective programs 54.

[0041] Rating information 56 may include, for example, numeric ratings of the efficacy of each of the programs. Rating information 56 may also include a pain map that indicates regions of pain within the body of patient 14, and paresthesia maps for each program that indicate regions of paresthesia resulting from delivery of neurostimulation according to that program. Rating information 56 may include numeric calculations of overlap between the pain map and the paresthesia map for each program. Processor 50 may receive rating information 56 from either or both of the clinician and patient 14. Exemplary techniques for collecting, calculating, and displaying such rating information are described in U.S. Patent No. 6,308,102, issued to Sieracki et al.

[0042] Longevity information 58 may include either or both of estimated drain rates and estimated longevities of battery 40 for each of programs 54. Processor 50 estimates a drain rate for battery 40 for each of programs 54 using well-known techniques for calculating battery drain rate based on the pulse amplitude, width and rate of a stimulation waveform, and the load presented to battery 40 during delivery of the stimulation waveform. In some embodiments, processor 50 further estimates a longevity of battery 40 for each program based on a capacity of battery 40, the estimated drain rate for each program, and a duty cycle for each program. Processor 50 may estimate the longevities as a time to explant, e.g., expiration of battery 40, based on constant delivery of stimulation according to programs 54, or an estimation of the amount of time patient 14 will use INS 12 over the course of a day, week, month, year, or the like. Processor 50 may determine the capacity of battery 40 from a look-up table stored in memory 62 based on device type information received from the clinician.

[0043] Processor 50 may determine the load presented to battery 40 for each of programs 54 using a variety of techniques. In some embodiments, processor 50 estimates the load based on the number of anodes and cathodes specified for the program, and an assumed per-electrode impedance, which may be stored in memory 62. The assumed per-electrode impedance value may be an average of impedances measured experimentally or gleaned from clinical data, and may be, for example, 700-1000 Ohms. Processor 50 may calculate the estimated load using the formula for parallel loads:

$$1/R_{(TOTAL)} = 1/R_{(CATHODES)} + 1/R_{(ANODES)}$$

where $R_{(TOTAL)}$ is the estimated load and each of $R_{(CATHODES)}$ and $R_{(ANODES)}$ is equal to the assumed per-electrode impedance value.

[0044] In some embodiments, the processor 50 alternatively or additionally estimates the load based on device configuration information, such as an INS type, lead type, and/or electrode locations. Processor 50 may receive the device configuration information from the clinician via user interface 52, and may identify components of the total load presented to the battery from look-up tables stored in memory 62 based on the received device configuration information. In other embodiments, to achieve greater accuracy in the drain rate estimate, processor 50 may direct INS 12 to measure, rather than estimate, the impedance presented by each of electrodes 30 coupled thereto, and receive the measured impedance values via telemetry circuit 60. Processor 50 may then determine the load for a particular program based on the measured impedances for the anodes and cathodes selected for that program using the formula for parallel loads illustrated above. In exemplary embodiments, processor 50 directs INS 12 to measure impedances before testing of programs 54.

[0045] Processor 50 may include a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or the like. A memory 62 may include program instructions that, when executed by processor 50, cause programming device 20 to perform the functions ascribed to programming device 20 herein. Memory 62 may include any volatile, non-volatile, fixed, removable, magnetic, optical, or electrical media, such as a RAM, ROM, CD-ROM, hard disk, removable magnetic disk, memory cards or sticks, NVRAM, EEPROM, flash memory, and the like.

[0046] FIG. 4 is a diagram illustrating an example graphical user interface (GUI) 70 that programming device 20, and more particularly processor 50 of programming device 20, may present to the clinician via user interface 52, e.g., via display 22. In some embodiments, processor 50 presents the estimated battery drain rates to the clinician via user interface 52. In other embodiments, processor 50 presents battery longevities instead of or in addition to the drain rates via user interface 52. In exemplary embodiments, processor 50 presents the drain rates and/or longevities within a listing of programs 54 tested on patient 14, which may be ordered according to the battery drain rates and/or battery longevities to allow a user to select a program that provides a low drain rate and high longevity.

[0047] In the illustrated embodiment, processor 50 presents a list 72 of programs 54 tested on patient 14 that includes longevities estimated for each of the programs 54. As illustrated in FIG. 4, the battery longevities may be presented to the user as an estimated number of years until explant. Processor 50 also presents rating information 56, which in this case is a numeric efficacy rating, for each program to the clinician within list 72. In exemplary embodiments, the clinician may order list 72 based on either or both of rating and longevity, to more easily compare programs and to, for example, select a program that provides better longevity from among those with similar ratings.

[0048] Each item in list 72 may be selected by the clinician to obtain additional information. For example, the clinician may click on program "1" to determine the details associated with program 1, such as the electrode configuration, amplitude, frequency, and pulse width. In this manner, the clinician can readily assess not only the drain rate, battery longevity and rating associated with each program, but also the underlying details of the program itself.

[0049] FIG. 5 is a flow chart illustrating an example operation of programming device 20 to present battery longevity information 58 to a user during a programming session. Processor 50 selects a program 54 to test on patient 14 from among programs 54 specified by the clinician (80), and provides the program to INS 12 via telemetry circuit 60 so that INS 12 may deliver neurostimulation to patient 14 according to the selected program (82). Processor 50 may select the program 54 based on input received from the clinician via user interface 52, or automatically from a listing of specified programs 54. Processor 50 receives rating information 56 for the program from one or both of the clinician and patient 14 via user

interface 52, and stores the rating information 56 within memory 62 in association with the program 54 (84).

[0050] Processor 50 continues to select programs 54 to test until either no more specified programs 54 remain to be tested or the clinician indicates that testing of programs is complete (86). When testing of programs 54 is complete, processor 50 estimates battery longevities for each of the tested programs, and stores the longevities as longevity information 58 in association with the respective programs 54 (88). Processor 50 estimates a drain rate for each of the programs, and estimates the longevities from the drain rates, as described above. Further, processor 50 may estimate drain rates and longevities according to any of the techniques described above. Processor 50 presents a sortable list 72 of tested programs 54, and associated rating information 56 and estimated longevities 58 to the clinician via user interface 52 (90).

[0051] Processor 50 may estimate drain rates and/or longevities at any time prior to, during, or following testing of programs 54. However, estimation of drain rates and/or longevities after testing of programs may allow changes made to the parameters of the programs 54 during testing, e.g., manipulation of amplitude, to be considered. Further, as indicated above, processor 50 need not estimate or display longevities. Rather processor 50 may simply display the estimated drain rates to the clinician.

[0052] FIG. 6 is a flow diagram illustrating another example operation of programming device 20 during a programming session. Specifically, FIG. 6 illustrates operation of programming device 20 to present longevity information 58 for a subset of tested programs 54 that provide acceptable stimulation. Operation of programming device 20 in this manner allows a user, such as a clinician, to first identify a subset of acceptable programs 54 from among those tested based on rating information 56, and then select programs for long-term use from the subset based on longevity. Sequential presentation of rating information 56 and longevity information 58 may allow the user to more easily identify programs that are both efficacious and provide desirable longevity, while allowing programming device 20 to only estimate battery drains, and in some cases longevities, for a subset of the programs tested during the programming session.

[0053] During the programming session for IMD 12, programming device 20 tests programs 54by directing IMD 12 to deliver neurostimulation to patient 14 according to programs

54(100). Programming device 20 collects rating information 56 relating to the efficacy of programs 54 from at least one of the clinician and patient 14 during testing of programs 54, as described above. After programs 54 have been tested, programming device 20 displays a list of the tested programs 54 ordered according to rating information 56 (102), and receives selections made by a user, such as the clinician, from the list (104).

[0054] Programming device 20 estimates drain rates and in some embodiments longevities, i.e., longevity information 58, for the selected programs, and displays a list of the selected programs ordered according the longevity information 58 (106). Programming device 20 receives one or more selections made by the clinician from the list, and provides the selected programs to IMD 12 via device telemetry for long-term use in delivery of neurostimulation therapy to patient 14 (108). In some embodiments, programming device 20 may also store highly rated programs with desirable longevities from the subset list within memory 62, or some other memory, such as a memory accessed via a network, for later selection by the clinician or patient 14 during a follow-up visit.

[0055] Various embodiments of the invention have been described. However, those skilled in the art will appreciate that various modifications may be made to the described embodiments without departing from the scope of the invention. For example, although estimation of drain rates and battery longevities, and presentation of such battery longevity information has been described herein as being performed by a single programming device, the invention is not so limited. Rather, such functions may be performed by two or more computing devices, which may communicate via a wired or wireless connection, or via a network. These and other embodiments are within the scope of the following claims.

CLAIMS:

1. A method comprising:

directing an implantable neurostimulator to deliver neurostimulation according to a plurality of programs during a programming session, each of the programs including a plurality of parameters that define delivery of neurostimulation according to that program;

estimating a battery drain rate for each of the programs based on the parameters for that program; and

presenting battery longevity information for each of the programs to a user based on the battery drain rates.

2. The method of claim 1, wherein the parameters for each of the programs include at least one of a pulse amplitude, a pulse width, a pulse rate, and a duty cycle.

3. The method of claim 1, wherein the parameters for each of the programs include a number of anodes and a number of cathodes for delivery of neurostimulation according to that program, and estimating a battery drain rate for one of the programs comprises:

estimating a load for the program based on the number of anodes and the number of cathodes; and

estimating the battery drain rate based on the estimated load.

4. The method of claim 3, wherein estimating a load comprises estimating the load based on an assumed per-electrode impedance.

5. The method of claim 1, wherein estimating a battery drain rate for one of the programs comprises:

receiving device configuration information;

estimating a load for the program based on the device configuration information; and

estimating the battery drain rate based on the estimated load.

6. The method of claim 5, wherein the device configuration information includes at least one of an implantable neurostimulator type, a lead type, and electrode locations.

7. The method of claim 1, wherein the parameters for each of the programs include an identification of anodes and cathodes for delivery of neurostimulation according to that program, and estimating a battery drain rate for one of the programs comprises:

measuring an impedance for each of the anodes and cathodes identified by the program;

calculating a load based on the measured impedances; and

estimating the battery drain rate based on the load.

8. The method of claim 1, wherein presenting battery longevity information for each of the programs to a user comprises presenting the battery longevity information within a list of the programs.

9. The method of claim 8, further comprising ordering the list according to the battery longevity information.

10. The method of claim 8, further comprising:

receiving rating information for each of the programs; and

presenting the rating information within the list.

11. The method of claim 10, further comprising ordering the list according to at least one of the battery longevity information and the rating information.

12. The method of claim 10, wherein the rating information for each of the programs includes at least one of an efficacy score and an estimation of overlap of pain and paresthesia.

13. The method of claim 1, further comprising:

receiving rating information for each of the programs;

presenting a first list of the tested programs, the first list including the rating information and ordered according to the rating information;

receiving selections made by the user from the first list;

presenting a second list that includes the programs selected from the first list and the longevity information associated with the selected programs, the second list ordered according to the longevity information;

receiving a selection made by the user of at least one program from the second list; and

programming the implantable neurostimulator with the selected program.

---

14. The method of claim 13, wherein estimating a battery drain rate for each of the programs comprises estimating the drain rate for each of the programs selected from the first list upon selection from the first list.

15. The method of claim 13, further comprising storing at least some of the programs from the second list within a memory.

16. The method of claim 1, wherein presenting battery longevity information to a user comprises presenting the battery drain rates.

17. The method of claim 1, further comprising estimating battery longevities for each of the programs based on the battery drain rates for each of the programs, wherein presenting the battery longevity information to a user comprises presenting the battery longevities.

18. The method of claim 1, wherein presenting battery longevity information to a user comprises presenting an estimated length of battery service.

19. The method of claim 1, further comprising receiving selection of the parameters for each of the programs from the user.

20. A programming device comprising:

a telemetry circuit;

a user interface; and

a processor to direct an implantable neurostimulator to deliver neurostimulation according to a plurality of programs during a programming session via the telemetry circuit, each of the programs including a plurality of parameters that define delivery of neurostimulation according to that program, estimate a battery drain rate for each of the programs based on the parameters for that program, and present battery longevity information to a user via the user interface based on the estimated battery drain rates.

21. The programming device of claim 20, wherein the parameters for each of the programs include at least one of a pulse amplitude, a pulse width, a pulse rate, and a duty cycle.

22. The programming device of claim 20, wherein the parameters for each of the programs include a number of anodes and a number of cathodes for delivery of neurostimulation according to that program, and the processor estimates a load for one of the programs based on the number of anodes and the number of cathodes for the program, and estimates the battery drain rate for the program based on the estimated load.

23. The programming device of claim 22, further comprising a memory to store an assumed per-electrode impedance, wherein the processor estimates the load based on the assumed per-electrode impedance.

24. The programming device of claim 20, wherein the processor receives device configuration information, estimates a load for one of the programs based on the device configuration information, and estimates a battery drain rate for the program based on the estimated load.

25. The programming device of claim 24, wherein the device configuration information includes at least one of an implantable neurostimulator type, a lead type, and electrode locations.

26. The programming device of claim 24, wherein the processor receives at least some of the device configuration information from the user via the user interface.

27. The programming device of claim 20, wherein the parameters for each of the programs include an identification of anodes and cathodes for delivery of neurostimulation according to that program, and the processor controls the implantable neurostimulator to measure the impedance for each of the anodes and cathodes identified by one of the programs, calculates a load for the program based on the measured impedances, and estimates the battery drain rate for the program based on the load.

28. The programming device of claim 20, wherein the processor presents the battery longevity information within a list of the programs.

29. The programming device of claim 28, wherein the processor orders the list according to the battery longevity information.

30. The programming device of claim 28, wherein the processor receives rating information for each of the programs, and presents the rating information within the list.

31. The programming device of claim 30, wherein the processor orders the list according to at least one of the battery longevity information and the rating information.

32. The programming device of claim 30, wherein the rating information for each of the programs includes at least one of an efficacy score and an estimation of overlap of pain and paresthesia.

33. The programming device of claim 20, wherein the processor receives rating information for each of the programs, presents a first list of the tested programs that includes the rating information and is ordered according to the rating information, receives selections made by the user from the first list, presents a second list that includes the programs selected from the first list and the longevity information associated with the selected program, the second list ordered according to the longevity information, receives a selection made by the user of at least one program from the second list, and programs the implantable neurostimulator with the selected program via the telemetry circuit.

34. The programming device of claim 33, wherein the processor estimates drain rates for each of the programs selected from the first list upon selection.

35. The programming device of claim 33, further comprising a memory to store at least some of the programs from the second list.

36. The programming device of claim 20, wherein the battery longevity information comprises the estimated battery drain rates.

37. The programming device of claim 20, wherein the processor estimates battery longevities for each of the programs based on the battery drain rates for each of the programs, and the battery longevity information comprises the estimated battery longevities.

38. The programming device of claim 20, wherein processor presents an estimated length of battery service for each of the programs to the user via the user interface.

39. The programming device of claim 20, wherein the processor receives selection of the parameters for each of the programs from the user via the user interface.

40. A computer-readable medium comprising instructions that cause a programmable processor to:

direct an implantable neurostimulator to deliver neurostimulation according to a plurality of programs during a programming session, each of the programs including a plurality of parameters that define delivery of neurostimulation according to that program;

estimate a battery drain rate for each of the programs based on the parameters for that program; and

present battery longevity information to a user based on the estimated battery drain rates.

41. The computer-readable medium of claim 40, wherein the parameters for each of the programs include at least one of a pulse amplitude, a pulse width, a pulse rate, and duty cycle.

42. The computer-readable medium of claim 40, wherein the parameters for each of the programs include a number of anodes and a number of cathodes for delivery of neurostimulation according to that program, and the instructions that cause a programmable processor to estimate a battery drain rate for one of the programs comprise instructions that cause a programmable processor to:

estimate a load for the program based on the number of anodes and the number of cathodes; and

estimate the battery drain rate based on the estimated load.

43. The computer-readable medium of claim 42, wherein the instructions that cause a programmable processor to estimate a load comprise instructions that cause a programmable processor to estimate the load based on an assumed per-electrode impedance.

44. The computer-readable medium of claim 40, further comprising instructions that cause a programmable processor to receive device configuration information, wherein the instructions that cause a programmable processor to estimate a battery drain rate for one of the programs comprise instructions that cause a programmable processor to:

estimate a load based on the device configuration information; and

estimate the battery drain rate for the program based on the estimated load.

45. The computer-readable medium of claim 44, wherein the device configuration information includes at least one of an implantable neurostimulator type, a lead type, and electrode locations.

46. The computer-readable medium of claim 40, wherein the parameters for each of the programs include an identification of anodes and cathodes for delivery of neurostimulation according to that program, and the instructions that cause a programmable processor to estimate a battery drain rate for one of the programs comprise instructions that cause a programmable processor to:

control the implantable neurostimulator to measure the impedance for each of the anodes and cathodes identified by the program;

estimate a load for the program based on the measured impedances; and

estimates the battery drain rate for the program based on the estimated load.

47. The computer-readable medium of claim 40, wherein the instructions that cause a programmable processor to present battery longevity information comprise instructions that cause a programmable processor to present the battery longevity information within a list of the programs.

48. The computer-readable medium of claim 47, further comprising instructions that cause a programmable processor to order the list according to the battery longevity information.

49. The computer-readable medium of claim 47, further comprising instructions that cause a programmable processor to:

receive rating information for each of the programs; and

present the rating information within the list.

50. The computer-readable medium of claim 49, further comprising instructions that cause a programmable processor to order the list according to at least one of the battery longevity information and the rating information.

51. The computer-readable medium of claim 49, wherein the rating information for each of the programs includes at least one of an efficacy score and an estimation of overlap of pain and paresthesia.

52. The computer-readable medium of claim 40, further comprising instructions that cause a programmable processor to:

receive rating information for each of the programs;

present a first list of the tested programs, the first list ordered according to the rating information;

receive selections made by the user from the first list;

present a second list that includes the programs selected from the first list and the longevity information associated with the programs selected from the first list, the second list ordered according to the longevity information;

receive selection of at least one program from the second list made by the user; and

program the implantable neurostimulator with the selected program.

53. The computer-readable medium of claim 52, wherein the instructions that cause a programmable processor to estimate a battery drain rate for each of the programs comprise instructions that cause a programmable processor to estimate the drain rate for each of the programs selected from the first list upon selection from the first list.

54. The computer-readable medium of claim 52, further comprising instructions that cause a programmable processor to store at least some of the programs from the second list in a memory.

55. The computer-readable medium of claim 40, wherein the instructions that cause a programmable processor to display battery longevity information comprise instructions that cause a programmable processor to display the estimated drain rates.

56. The computer-readable medium of claim 40, further comprising instructions that cause a programmable processor to estimate battery longevities for each of the programs based on the battery drain rates for each of the programs, wherein the instructions that cause a programmable processor to present battery longevity information comprise instructions that cause a programmable processor to present the estimated battery longevities.

57. The computer-readable medium of claim 40, wherein the instructions that cause a programmable processor to present battery longevity information to a user comprise instructions that cause a programmable processor to present an estimated length of battery service for each of the programs.

58. The computer-readable medium of claim 40, further comprising instructions that cause a programmable processor to receive selection of the parameters for each of the programs from the user.

IMPLANTABLE NEUROSTIMULATOR PROGRAMMING WITH BATTERY LONGEVITY INDICATION

ABSTRACT

A programming device used to program an implantable neurostimulator (INS) presents battery longevity information to a user to assist the user in selecting a program for the INS. The programming device directs the INS to deliver neurostimulation therapy according to a plurality of programs during a programming session. Each of the programs includes parameters that define the neurostimulation delivered according to that program. For example, each program may include as parameters a voltage or current pulse amplitude, a pulse width, a pulse rate, and a duty cycle. The program may also identify as parameters the electrodes selected from a set coupled to the INS and their polarities, e.g., anode or cathode, for delivery of neurostimulation according to that program. The programming device estimates battery drain rates for each of the programs tested during the programming session based on the parameters for that program, and presents battery longevity information to a user based on the estimated battery drain rates.

Attorney Docket No. 1023-223US01/P-11559.00

SHUMAKER & SIEFFERT, P.A.

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and that I believe I am an original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: IMPLANTABLE NEUROSTIMULATOR PROGRAMMING WITH BATTERY LONGEVITY INDICATION

The specification of which
a. ☒ is attached hereto
b. ☐ was filed on as application serial no. and was amended on (if applicable) or
c. ☐ was (in the case of a PCT-filed application) described and claimed in international no. filed and as amended on (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. ☒ no such applications have been filed.
b. ☐ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS
60/448,457	21 February 2003	
60/503,207	15 September 2003	

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James J. Bindseil	Reg. No. 42,326	Kenneth Collier	Reg. No. 34,982
Daniel Greeninger	Reg. No. 48,464	James R. Keogh	Reg. No. 44,824
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Thomas F. Woods	Reg. No. 36,726	Mark E. O'Connor	Reg. No. 40,108
Richard Yoon	Reg. No. 42,247	Michael Soldner	Reg. No. 41,455

as my/our attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Shumaker & Sieffert, P.A. to the contrary.

Please direct all correspondence in this case to:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Signature of Inventor:				Date:

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Signature of Inventor:			Date:	

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Signature of Inventor: David D. Brigham			Date: 10-23-03	

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;

or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application:

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

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TITLE: IMPLANTABLE NEUROSTIMULATOR PROGRAMMING WITH BATTERY LONGEVITY INDICATION
ATTORNEY/AGENT: JASON D. KELLY
REG. NO. 54,213 TELEPHONE: 651.735.1100
DOCKET NO.: 1023-223US01 / P-11559.00 SHEET 1 OF 6

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NOV 25 2003
PATENT & TRADEMARK OFFICE

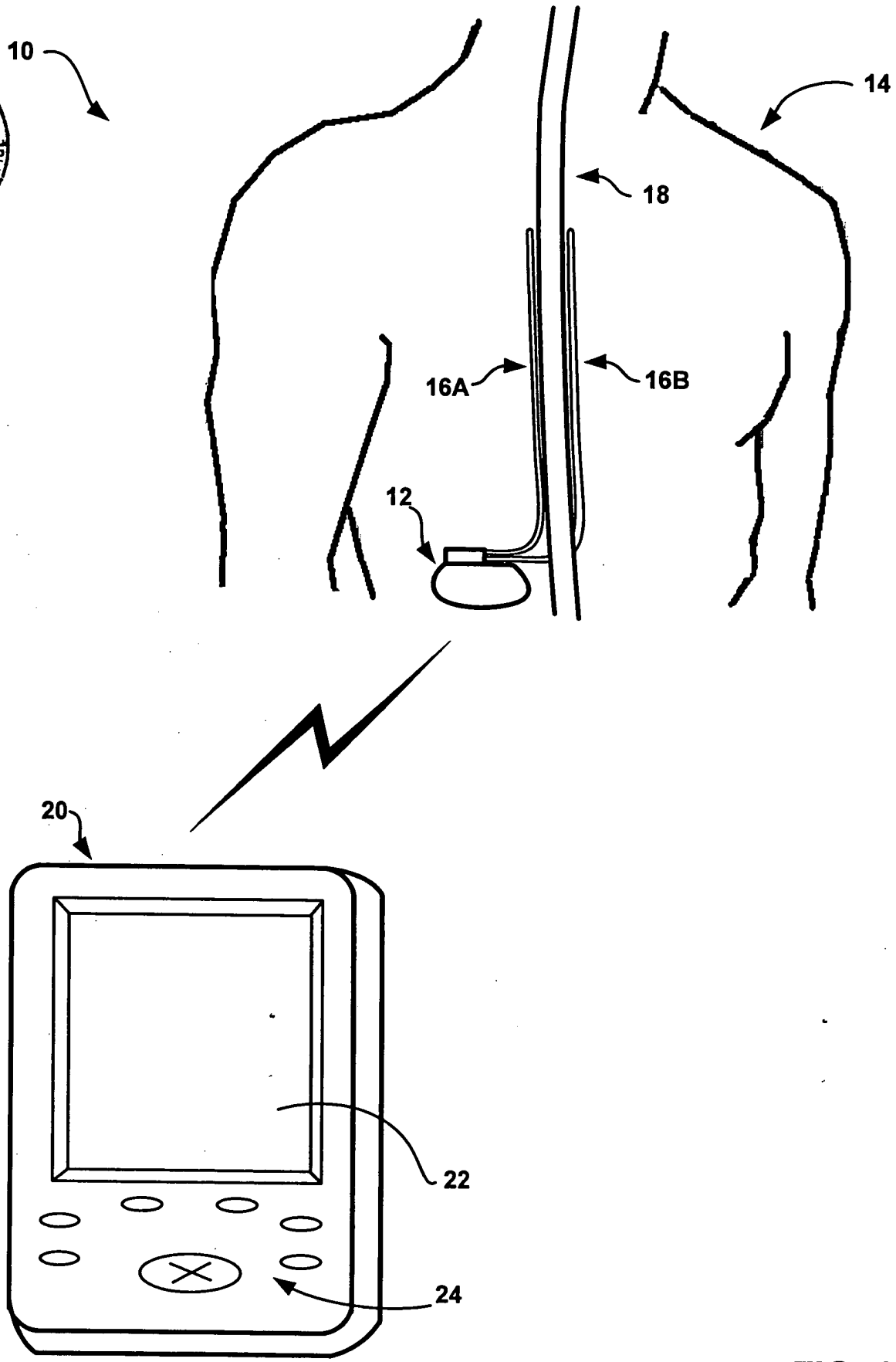

FIG. 1

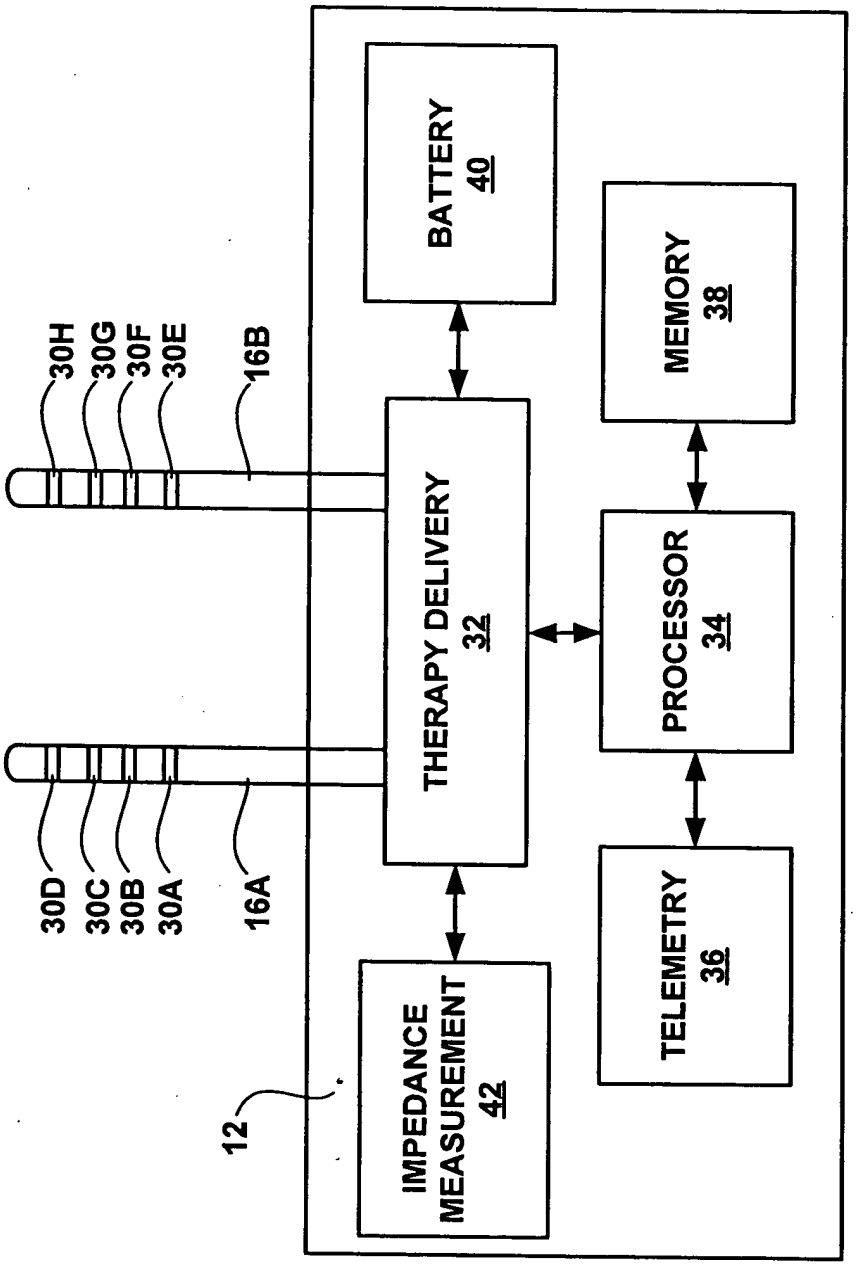
BATTERY
40
MEMORY
38
30H
30G
30F
30E
16B
THERAPY DELIVERY
32
PROCESSOR
34
30D
30C
30B
30A
16A
TELEMETRY
36
12
IMPEDANCE
MEASUREMENT
42

FIG. 2

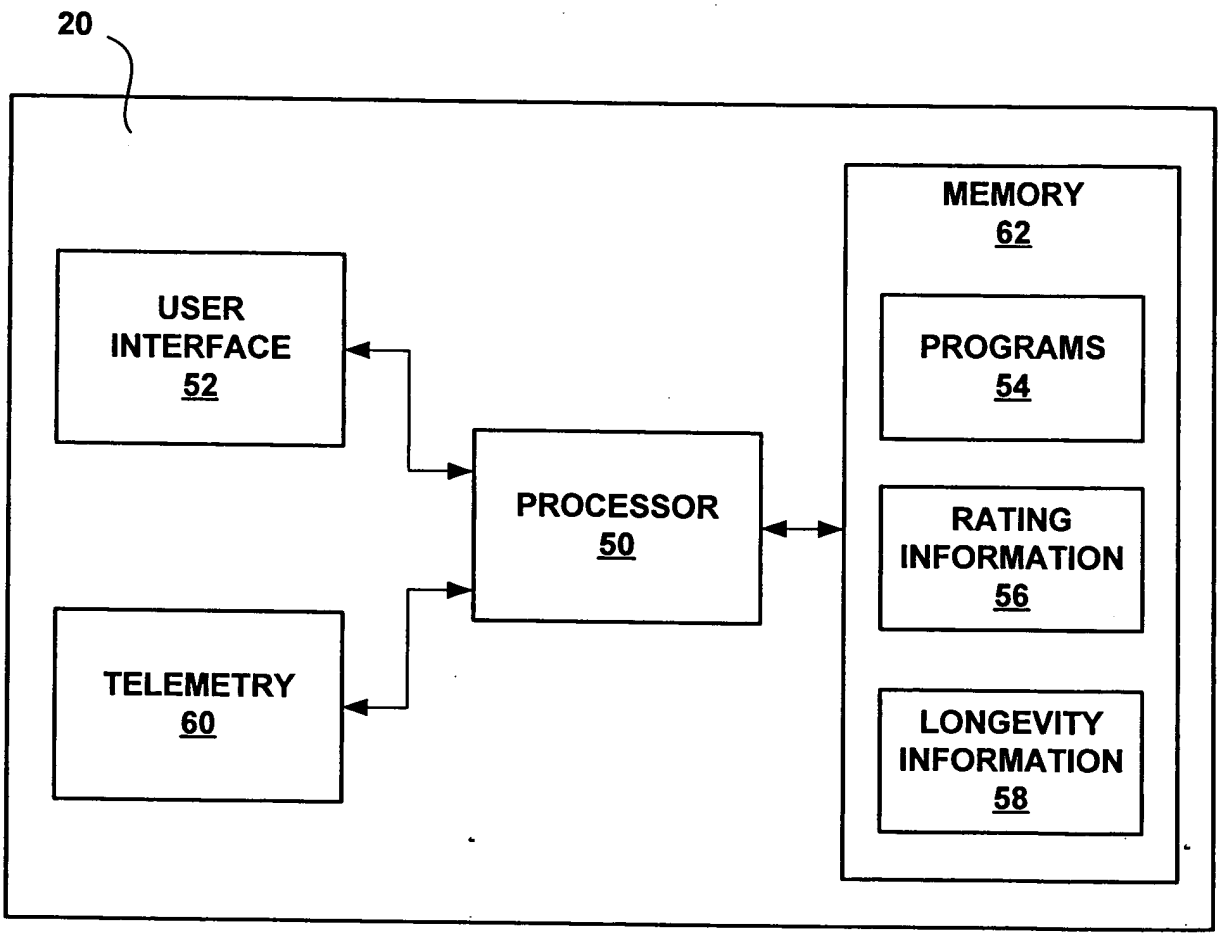
20
MEMORY
62
USER INTERFACE
52
PROGRAMS
54
PROCESSOR
50
RATING INFORMATION
56
TELEMETRY
60
LONGEVITY INFORMATION
58

FIG. 3

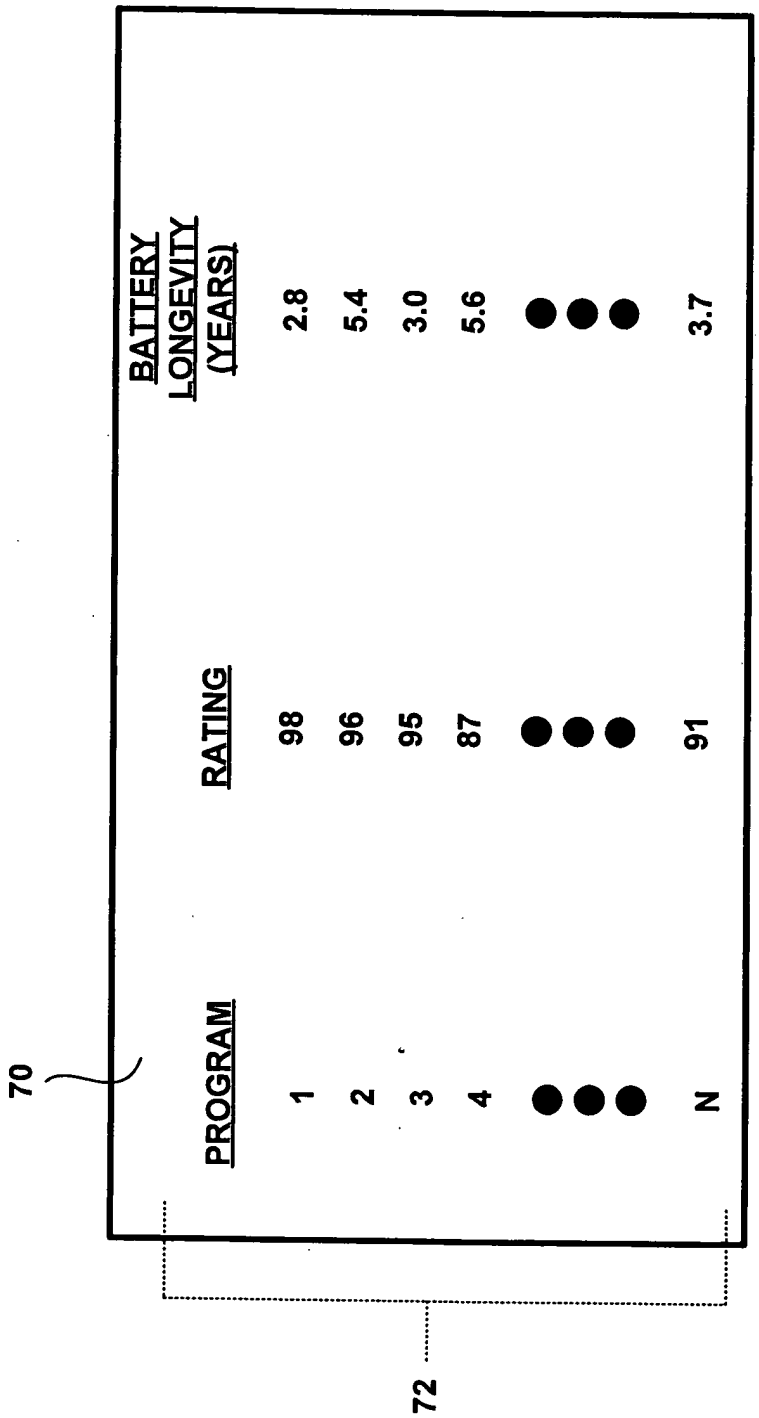
70
PROGRAM
RATING
BATTERY LONGEVITY (YEARS)
1
98
2.8
2
96
5.4
3
95
3.0
4
87
5.6
N
91
3.7
72

FIG. 4

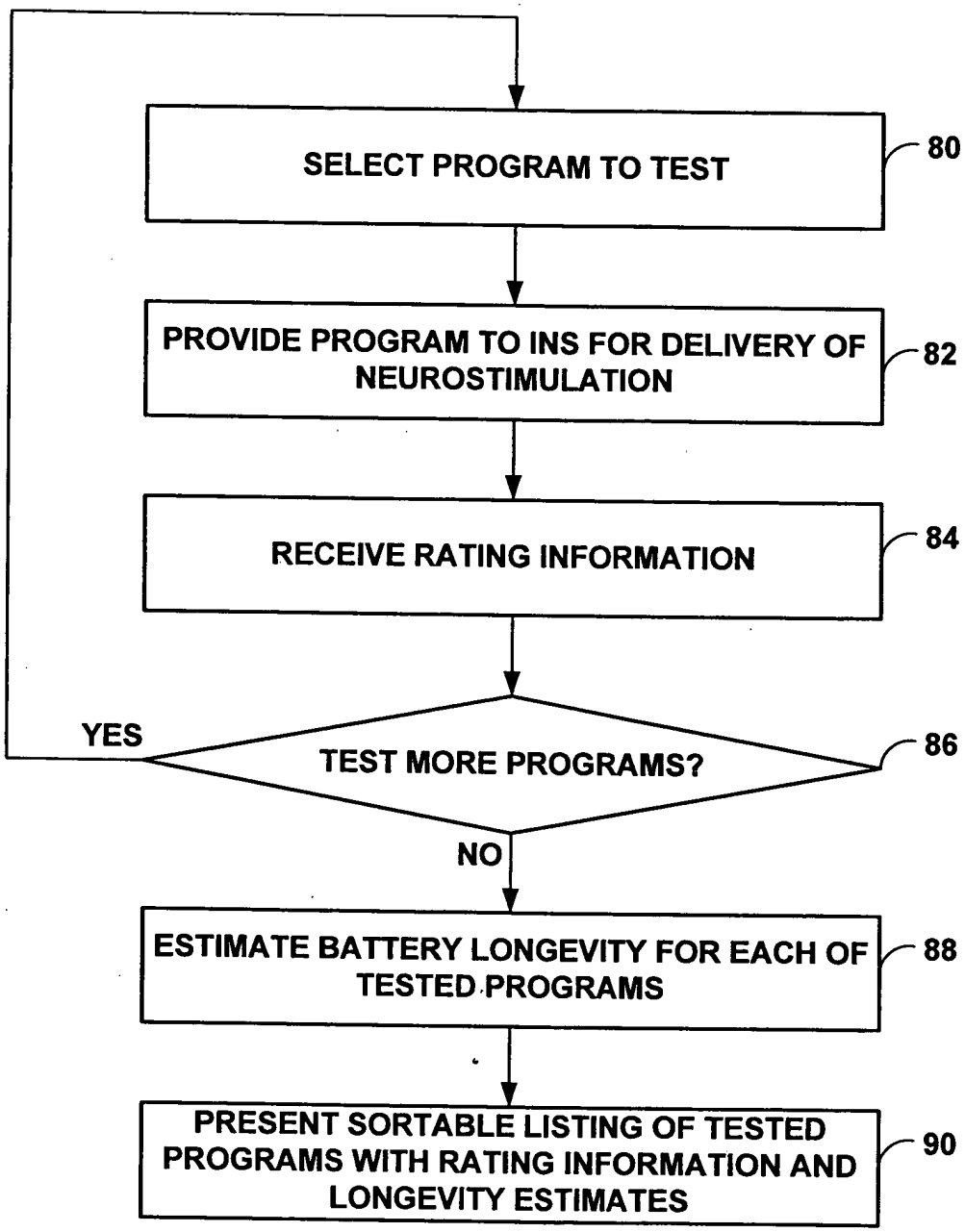
SELECT PROGRAM TO TEST
80
PROVIDE PROGRAM TO INS FOR DELIVERY OF NEUROSTIMULATION
82
RECEIVE RATING INFORMATION
84
YES
TEST MORE PROGRAMS?
86
NO
ESTIMATE BATTERY LONGEVITY FOR EACH OF TESTED PROGRAMS
88
PRESENT SORTABLE LISTING OF TESTED PROGRAMS WITH RATING INFORMATION AND LONGEVITY ESTIMATES
90

FIG. 5

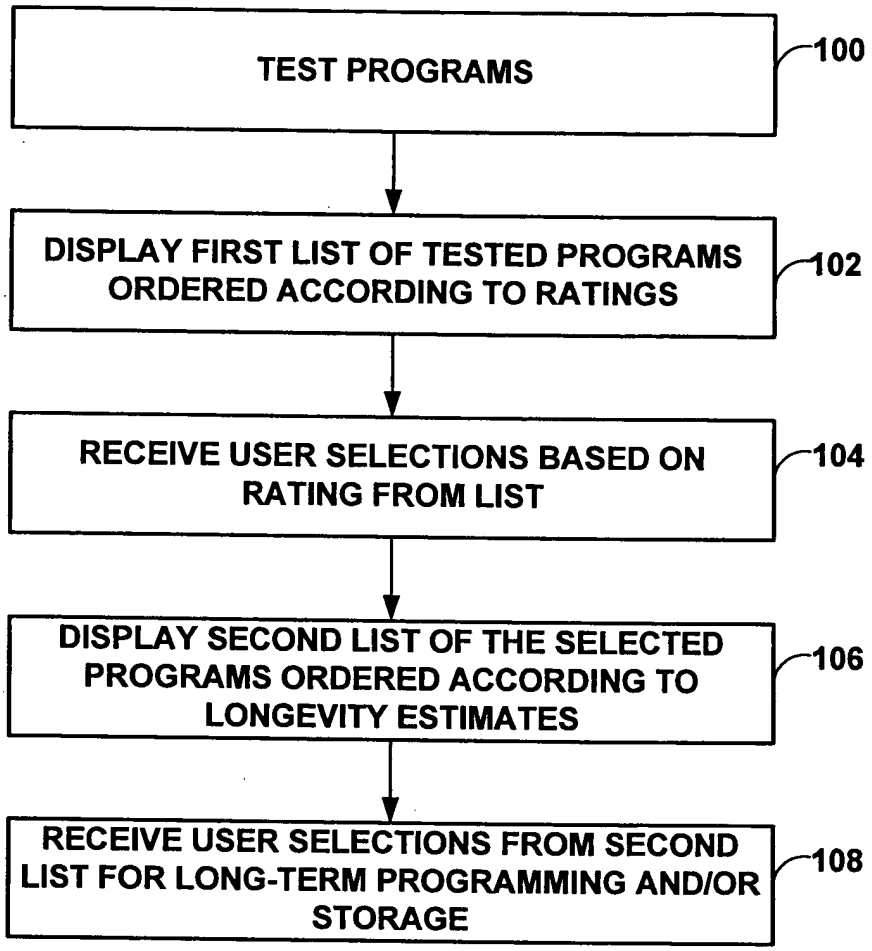
TEST PROGRAMS
100
DISPLAY FIRST LIST OF TESTED PROGRAMS ORDERED ACCORDING TO RATINGS
102
RECEIVE USER SELECTIONS BASED ON RATING FROM LIST
104
DISPLAY SECOND LIST OF THE SELECTED PROGRAMS ORDERED ACCORDING TO LONGEVITY ESTIMATES
106
RECEIVE USER SELECTIONS FROM SECOND LIST FOR LONG-TERM PROGRAMMING AND/OR STORAGE
108

FIG. 6

Docket No. 1023-223US01

FORM PTO-1595
(Rev. 6-93)
OMB No. 0651-0011 (exp. 4/94)

RECORDATION FORM COVER SHEET
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Name of conveying party(ies):	Execution Date (Month/Day/Year)	Name and address of receiving party(ies):
Richard B. North Jeffrey M. Sieracki David D. Brigham	10/23/03	Medtronic, Inc. 710 Medtronic Parkway Minneapolis,MN 55432
Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No		Additional name(s) & address(es) attached? ☐ Yes ☒ No

Nature of conveyance:

☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Other:

Submission Type:

☒ New ☐ Resubmission (Non-Recordation): Document ID #
☐ Correction of PTO Error: Reel # ___ Frame #
☐ Corrective Document: Reel # ___ Frame #

☒ This document is being filed with a new patent application on October 29, 2003.
☐ This document is to be recorded against the following patent application or patent:

Patent Application No.(s)

Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

Name and address of party to whom correspondence concerning document should be mailed:

Name: Jason D. Kelly
Address: Shumaker & Sieffert, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, MN 55125

Total number of applications and patents involved: 1

Total fee (37 CFR 3.41): $40.00

☐ Enclosed
☒ Authorized to be charged to deposit account

Please charge any additional fees or credit any overpayments to our Deposit account number: 50-1778

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Statement and signature:

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Jason D. Kelly
Name of Person Signing
Reg. No. 54,213

Jason D Kelly
Signature

October 29, 2003
Date

Total number of pages of the attached conveyance document including any attachments: 2

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Alexandria, VA 22313-1450

Public burden reporting for this sample cover sheet is estimated to average about 30 minutes per document to be recorded, including time for reviewing the document and gathering the data needed, and completing and reviewing the sample cover sheet. Send comments regarding this burden estimate to the U.S. Patent and Trademark Office, Office of information systems, PK2-1000C, Alexandria, VA 22313-1450, and to the Office of Management and Budget, Paperwork Reduction Project (0651-0011), Washington, D.C. 20503.

Attorney Docket No.: 1023-223US01/P-11559.00

ASSIGNMENT

For valuable consideration, we, Richard B. North of 1100 Copper Hill Road, Baltimore, MD 21209, Jeffrey M. Sieracki of 13506 Collingwood Terrace, Silver Spring, MD 20904 and David D. Brigham of 9151 Gracious End Court, Columbia, MD 21046, hereby assign to: Medtronic, Inc., having a place of business at: 710 Medtronic Parkway, Minneapolis, MN 55432; and its successors and assigns (collectively hereinafter called "the Assignee"), the entire right, title and interest throughout the world in the inventions and improvements which are the subject of an application for United States Patent signed by us, entitled IMPLANTABLE NEUROSTIMULATOR PROGRAMMING WITH BATTERY LONGEVITY INDICATION; this assignment including said application, any and all United States and foreign patents, utility models, and design registrations granted for any of said inventions or improvements, and the right to claim priority based on the filing date of said application under the International Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, the European Patent Convention, and all other treaties of like purposes; and we authorize the Assignee to apply in all countries in our name or in its own name for patents, utility models, design registrations and like rights of exclusion and for inventors' certificates for said inventions and improvements; and we agree for ourselves and our respective heirs, legal representatives and assigns, without further compensation to perform such lawful acts and to sign such further applications, assignments, Preliminary Statements and other lawful documents as the Assignee may reasonably request to effectuate fully this assignment.

Date: _____ _____

Richard B. North

State of)
) ss:
County of)

On this _____ day of _____, 20___, before me, _____, Notary Public, personally appeared Richard B. North personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity, and that by his/her/their signature on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

_____

Signature of Notary Public
My Commission Expires:

Date: _____

_____
Jeffrey M. Sieracki

State of)
) ss:
County of)

On this _____ day of _____, 20___, before me, _____, Notary Public, personally appeared Jeffrey M. Sieracki personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity, and that by his/her/their signature on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

_____
Signature of Notary Public
My Commission Expires:

Date: 10-23-03

David D. Brigham
David D. Brigham

State of Maryland)
) ss:
County of Harford)

On this 23rd day of October, 2003, before me, Frank R. Ernest, Notary Public, personally appeared David D. Brigham personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity, and that by his/her/their signature on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

_____
Signature of Notary Public
My Commission Expires: 03/01/2006.

Exhibit B

The Patent and Trademark Office date stamp sets forth the date of receipt of:

☒ Transmittal Letter
☒ Utility Patent Application
☒ Assignment Recordation Cover Sheet

Applicant: Richard B. North; Jeffrey M. Sieracki; David D. Brigham
Docket No.: 1023-223US01
Title: IMPLANTABLE NEUROSTIMULATOR PROGRAMMING WITH BATTERY LONGEVITY INDICATION
Pgs of Specification 25
(including Claims and Abstract)
Number of Claims: 58 Sheets of Drawings: 6
☒ Declaration ☒ Assignment ☒ Certif. Of Mailing
Date Mailed: October 29, 2003
Express Mail No.: ET987500483US

22154 U.S. PTO
10/696501
103003

Exhibit C

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Time In: 1725 ☐ AM ☑ PM	Military: ☐ 2nd Day ☐ 3rd Day	Return Receipt Fee	
Weight: lbs. 01 ozs.	Int'l Alpha Country Code	COD Fee	Insurance Fee
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Jason D. Kelly
Shumaker, Loffler PA
8425 Seasons Parkway
Suite 105
St. Paul, MN 55125
1023.223501

TO: (PLEASE PRINT) PHONE ( )

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA

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Exhibit D

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SAINT PAUL, Minnesota
551011438

10/29/2003 (651)293-6034 05:38:16 PM

Sales Receipt

Product Description	Sale Qty	Unit Price	Final Price
ALEXANDRIA VA 22313			$13.65
Express Mail PO-ADD Flat Rate			
Serial Number ET987500470US			
2nd Day Noon / Normal Delivery			
Paid by account: 1023-601USO2			$13.65
EMCA account number:			551177
ALEXANDRIA VA 22313			$13.65
Express Mail PO-ADD Flat Rate			
Serial Number ET987500483US			
2nd Day Noon / Normal Delivery			
Paid by account: 1023-223USO1			$13.65
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EMCA account number:			551177
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Express Mail PO-ADD Flat Rate			
Serial Number ET987500452US			
2nd Day Noon / Normal Delivery			
Paid by account: 1023-226USO1			$13.65
EMCA account number:			551177
ALEXANDRIA VA 22313			$13.65
Express Mail PO-ADD Flat Rate			
Serial Number ET987500466US			
2nd Day Noon / Normal Delivery			
Paid by account: 1023-224USO1			$13.65
EMCA account number:			551177
ALEXANDRIA VA 22313			$13.65
Express Mail PO-ADD Flat Rate			
Serial Number ET987500449US			
2nd Day Noon / Normal Delivery 1023-227USO1			
Paid by account:			$13.65
EMCA account number:			551177
ALEXANDRIA VA 22313			$13.65
Express Mail PO-ADD Flat Rate			